



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference YCT-921	FOR FURTHER ACTION	See Form PCT/IPEA/416																								
International application No. PCT/JP2004/005397	International filing date (day/month/year) 15.04.2004	Priority date (day/month/year) 15.04.2003																								
International Patent Classification (IPC) or national classification and IPC																										
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input checked="" type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) <u>1</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table border="0"><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																									
Name and mailing address of the IPEA/JP	Authorized officer																									
Facsimile No.	Telephone No.																									

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/005397

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
 - ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☒ the international application as originally filed/furnished
 - ☐ the description:
 - pages _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____
 - ☐ the claims:
 - nos. _____ as originally filed/furnished
 - nos.* _____ as amended (together with any statement) under Article 19
 - nos.* _____ received by this Authority on _____
 - nos.* _____ received by this Authority on _____
 - ☐ the drawings:
 - sheets _____ as originally filed/furnished
 - sheets* _____ received by this Authority on _____
 - sheets* _____ received by this Authority on _____
 - ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 10

YES

Claims 1-9, 11-13

NO

Inventive step (IS)

Claims 10

YES

Claims 1-9, 11-13

NO

Industrial applicability (IA)

Claims 1-13

YES

Claims

NO

2. Citations and explanations (Rule 70.7)

Document 1: Canturk, Z. et al., "Effects of rhG-CSF on neutrophil functions and bone marrow parameters in diabetic rats", Endocrine Research, 1999, Vol. 25, No. 3 & 4, pages 381 to 395, (abstract) CAPLUS [online]; CAPLUS Accession No. 2000:28442

Document 2: Sato N., et al., "Effect of granulocyte-colony stimulating factor on generation of oxygen-derived free radicals and myeloperoxidase activity in neutrophils from poorly controlled NIDDM patients, Diabetes, 1997, Vol. 46, No. 1, pages 133 to 7

Document 1 cited in the international search report indicates that non-selective immunity may be improved by administering G-CSF to diabetes patients.

Document 2 indicates that G-CSF is effective in preventing bacterial infections in diabetes patients.

Claims 1 to 9 and 11 to 13

The invention set forth in claims 1 to 9 and 11 to 13 of this application pertain to a "diabetes remedy", "a

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

pancreatic Langerhans beta cell regenerant" and "an agent for suppressing the destruction of pancreatic Langerhans beta cells" containing stem cell mobilization factors such as granulocyte colony stimulating factor as active ingredients. However, the claims relating to these inventions all include medications used in the treatment of diabetes, and the active ingredient and applicable disorders are the same as for the inventions set forth in documents 1 and 2, therefore it is impossible to distinguish between the two.

Therefore the invention set forth in claims 1 to 9 and 11 to 13 lacks novelty and does not involve an inventive step in the light of documents 1 and 2.

Claim 10

The invention set forth in claim 10 is neither disclosed nor suggested in any of the documents cited in the international search report, and is therefore novel and involves an inventive step.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The claims of this application set forth a "stem cell mobilization factor" compound defined by desired properties, and said claims include the use of all compounds having said properties. However, only a small part of the claimed compounds are disclosed within the meaning of PCT Article 5, and the claims are not fully supported by the description within the meaning of PCT Article 6.

In addition, even taking into account common general technical knowledge at the time of filing, it is impossible to designate the range of compounds having the properties of a "stem cell mobilization factor", therefore the aforementioned claims do not fulfil the requirement of clarity within the meaning of PCT Article 6.

This written opinion was formed on the applicable scope of the international search report, i.e. when a granulocyte-colony stimulating factor is used.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."